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PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
David Ow	Art Unit: **1638**
Serial No. **09/911,088**	Examiner: **Helmer, Georgia L.**
Filed: **July 23, 2001**	
For: **Methods for the Replacement, Translocation and Stacking of DNA in Eukaryotic Genomes**	

RESPONSE TO OFFICE ACTION

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Election/Restriction requirement mailed on October 2, 2002, a response which is due November 2, 2000, Applicant elects, with traverse, Group I(A)(a)(ii) directed to Claims 1-36, 39 and 40 as they relate to ϕC31 integrase, Cre reversible recombinases and/or plant cells.

Applicant makes the above election with traverse. Applicant submits that the invention is a novel method for introducing polynucleotides into eukaryotic cells. The novelty of the invention lies at

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William L. Warren – Reg. 36,714

least in the use of an irreversible recombinase and two or more irreversible recombination sites in a receptor construct in addition to two or more complementary irreversible recombination sites in a donor construct. This novel method allows for the stable, site-specific replacement of a polynucleotide using a limited number of integration steps, which benefits are not provided in the prior art.

The Office Action states that restriction is required between the different irreversible recombinases, the reversible recombinases and the type of cell in which the recombination reaction takes place because "the different inventions have different modes of operation, different functions or different effects – the two sets of enzymes have different catalytic properties and produce different products, and the mammalian/plant cells are complex, living, eukaryotic cells."

Applicant respectfully submits that the restriction requirement does not meet the requirements set out in Chapter 800 of the MPEP, and accordingly requests that the Examiner review and withdraw the requirement. Section 803.01 of the MPEP states that there are two requirements for restriction between patentably distinct inventions: 1) the inventions must be independent or distinct as claimed and 2) there must be a serious burden on the examiner if restriction is required. Applicant first submits that the Examiner has not demonstrated that it would be a serious burden to search and examine all of the claims together. Three of the four groups of claims are within the same class and subclass, and therefore, easily searched together. The fourth group, Group II, is still within the same class as the other three groups of claims, and therefore, also easily searched with the other three groups.

Applicant also notes that Group II contains product by process claims. In order for an Examiner to restrict product by process claims from the process claims themselves, the Examiner must show that 1) the product *as claimed* can be made by another and materially different process or 2) that the process as claimed is not an obvious process of making the product and the process *as claimed* can

be used to make other and different products. (MPEP Section 806.05(f)). Applicant submits that the Examiner has not shown that either requirement is met by the claims of the present invention. Accordingly, Applicant respectfully requests that the Examiner remove the restriction requirement between Groups I-IV.

Applicant also submits that it is improper to make a restriction between the Markush groups found in groups (A)-(F) and (a)-(e). Section 803.02 of the MPEP states that "it is improper for the Office to refuse to examine that which applicant regard as their invention, unless the subject matter in a claim lacks unity of invention. Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial feature disclosed as being essential to that utility" (Citations omitted). Applicant submits that unity of invention exists in the present application because each of the members of the groups of irreversible recombinases and reversible recombinases share a common utility, respectively, and substantial features disclosed as being essential to that utility.

More specifically, Applicant submits that the recombinases in each category share the catalytic property that is essential to the invention. All of the irreversible recombinases create a recombination product that cannot undergo a second homologous recombination event following a first homologous recombination event. All of the reversible recombinases create a recombination product that can undergo a second homologous recombination event following a first homologous recombination event. These common properties are the ones upon which the invention relies, and accordingly, for the purposes of the present invention, the irreversible recombinases are catalytically identical and the reversible recombinases are catalytically identical. For at least these reasons, Applicant traverses the restriction requirement between the different irreversible and reversible recombinases in (A)-(F) and requests that the Examiner review and withdraw the requirement.

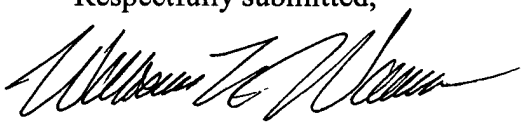
Finally, Applicant submits that the restriction between groups (i) and (ii), or mammalian and plant cells, is improper. The Office Action stated that "the different inventions have different modes of operation, different functions or different effects – ... the mammalian/plant cells are complex, living, eukaryotic cells." Applicant is unable to discern how this statement supports the restriction between mammalian and plant cells and submits that such statement does not meet the requirements of Section 816 of the MPEP. That section states that the "particular reasons relied upon by the examiner for holding that the invention as claimed are either independent or distinct should be concisely stated."

Applicant additionally submits that the invention does not have a different mode of operation, function or effect whether it is used in mammalian cells or plant cells. The mode of operation, function and effect are the same in mammalian and plants cells because both the irreversible and reversible recombinases act in the same manner, respectively, whether in a plant cell or a mammalian cell. More specifically, the irreversible recombinases create a recombination product in both mammalian and plant cells that cannot undergo a second homologous recombination event following a first homologous recombination event; and the reversible recombinases create a recombination product in both mammalian and plant cells that can undergo a second homologous recombination event following a first homologous recombination event. For at least these reasons, Applicant respectfully requests the removal of the restriction between mammalian and plant cells.

In summary, Applicant makes the above election with traverse. Applicant submits that each of the restrictions is improper and respectfully requests that the Examiner review and withdraw each restriction requirement. The foregoing is submitted as a full and complete Response to the Office Action mailed October 2, 2002. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to

Deposit Account No. 19-5029. The Examiner is invited and encouraged to contact the undersigned attorney of record if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,



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